Memo of Meeting

Date: April 25, 2002
Location: 1350 Piccard Drive, Rockville, Maryland 20850

Representing InfinityQS International, Inc.
7998 Donegan Dr.
Manassas, VA 20109

Jmichael A. Lyle, President/CEO
B.K. Im, Controller/CFO
Connie Davies, Sales Manager

Representing FDA:

David Doleski, Biologist, Center for Biologics Evaluation and Research
Allen Wynn, Consumer Safety Officer, (detailed to Office of Enforcement from) Center For Devices and Radiological Health
Scott MacIntire, Director, Division of Compliance Information and Quality Assurance, Office of Enforcement
Paul J. Motise, Consumer Safety Officer, Office of Enforcement

The meeting was held at the request of the InfinityQS representatives, to discuss their statistical process control software, InfinityQS2002, in the context of 21 CFR Part 11. The firm promotes its product as enabling their users to meet requirements of part 11. At the start of the meeting we explained that FDA does not formally review, approve or disapprove of products or services that enable people to comply with FDA regulations. We advised that the meeting would be an information exchange and that our comments should not be taken as formal FDA positions.

At the start of the meeting we also asked the representatives to tell us if they considered any information, including the contents of a product brochure they gave us, to be confidential, trade secret or otherwise of a nature that they would not want included in a publicly available memo of our meeting. The publication is attached.

The InfinityQS representatives explained that their company produces statistical process control software for a broad range of industries, most of which are not regulated by FDA. However, they commented that they wanted to expand into FDA regulated industries, help them meet the technical requirements of part 11 and have designed their software with that objective in mind. The software is written for Windows 95 thru XP platforms.

During the meeting we discussed the firm's validation efforts. The representatives said they would welcome customer audits of their software development activities. The firm has already been audited by one major pharmaceutical establishment and participates in the PDA shared audit repository program. The firm will also provide software functional specifications and test scripts.

Regarding audit trails, the representatives explained that the system implements a traceability table that records who wrote what and when. The audit trail records the operator's identity, the nature of the event (record creation, deletion or modification), a revision identifier to permit mapping of changes to particular operators, and the date and time of the event. Except for the system administrator, end users cannot access or delete the table. Changed data is written to the audit trail. We suggested that the changed record itself be flagged in some manner to indicate that a change is made so that reviewing the audit trail would not be the only way to notice that a change had been made.

A separate system access log records when users log in and out of the program.

Concerning electronic copies of the electronic records produced by the firm's software, the InfinityQS representatives said that the records could be exported to MS Excel format.

The system implements electronic signatures based on identification codes in combination with passwords. The representatives explained that the system allows administrators to configure various password security parameters, but that the company ships the software with those settings in an inactive (low security) mode. When security settings are active the passwords can be from 8 to 31 characters; inactive security allows fewer than 8. Password aging (security active) is set to 15 days to 365 days – less than 15 with security off. The program does not permit passwords to be the same as identification codes. In addition, attempts at unauthorized access (i.e., failed log-ins) are recorded to a log (configurable and set to 3 with security on—up to 99 allowable). A software utility is available to send an urgent message of a potential security breach to security managers. We suggested that the firm ship its product to FDA regulated establishments with the security settings active rather than inactive. We commented that although part 11 does not specify a minimum password length, we were unaware of any mainstream standards that advocated use of single character password, something that the system would allow as shipped.

With respect to the manifestation of electronic signatures, the representatives explained that the system displays the user's printed name, date and time of signing and, optionally, the cause for the signature.

The meeting lasted about two hours.

cc:
FDA Attendees
HFA-224
Part 11 Guidance Dockets

Doc ID InfinityQSMemoOfMeeting042502.doc
P. Motise 05/16/02